



DOCKET NO.: CEPH-2249/CP241

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of:

Craig Heacock, et al.

Application No.: 10/616,776

Filing Date: July 10, 2003

For: MODAFINIL PHARMACEUTICAL COMPOSITIONS

Confirmation No.: 1994

Group Art Unit: 1615

Examiner: Not Yet Assigned

DATE OF DEPOSIT:

July 15, 2005

I HEREBY CERTIFY THAT THIS PAPER IS BEING DEPOSITED WITH THE UNITED STATES POSTAL SERVICE AS FIRST CLASS MAIL, POSTAGE PREPAID, ON THE DATE INDICATED ABOVE AND IS ADDRESSED TO THE UNITED STATES PATENT AND TRADEMARK OFFICE, P.O. BOX 1450, ALEXANDRIA, VA 22313-1450.

Elizabeth A. McLoud

TYPED NAME: Elizabeth A. McLoud

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Pursuant to 37 CFR § 1.56 and in accordance with 37 CFR §§ 1.97-1.98, information relating to the above-identified application is hereby disclosed. Inclusion of information in this statement is not to be construed as an admission that this information is material as that term is defined in 37 CFR § 1.56(b).



In accordance with § 1.97(b), since this Information Disclosure Statement is being filed either within three months of the filing date of the above-identified application, within three months of the date of entry into the national stage of

the above identified application as set forth in § 1.491, before the mailing date of a first Office Action on the merits of the above-identified application, or before the mailing date of a first Office Action after the filing of request for continued examination under § 1.114, no additional fee is required.

- ☐ In accordance with § 1.97(c), this Information Disclosure Statement is being filed after the period set forth in § 1.97(b) above but before the mailing date of either a Final Action under § 1.116 or a Notice of Allowance under § 1.311, or before an action that otherwise closes prosecution in the application, therefore:

☐ Certification in Accordance with § 1.97(e) is attached; or

☐ The fee of **\$180.00** as set forth in § 1.17(p) is attached.

- ☐ In accordance with § 1.97(d), this Information Disclosure Statement is being filed after the mailing date of either a Final Action under § 1.113 or a Notice of Allowance under § 1.311 but before, or simultaneously with, the payment of the Issue Fee, therefore included are: Certification in Accordance with § 1.97(e); and the submission fee of **\$180.00** as set forth in § 1.17(p).

- ☒ Copies of reference numbers **21 – 49 and 63 - 71** listed on the attached Form PTO-1449 are enclosed herewith.

- ☒ Copies of reference numbers **50 - 62** on the attached Form PTO 1449 are not required to be submitted pursuant to 37 CFR § 1.98(a)(2)(i).

- ☐ Copies of references - are not being submitted because they were previously cited by or submitted to the U.S. Patent and Trademark Office in patent application number , filed for which a claim for priority under 35 U.S.C. § 120 has been made in the instant application.

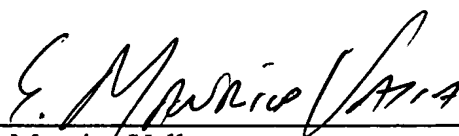
☐ The relevance of those listed references which are not in the English language is as follows:

There are no listed references which are not in the English language.

Please charge any deficiency or credit any overpayment to Deposit Account No. 23-3050. This form is submitted in duplicate.

Date:

7/15/05



S. Maurice Valla
Registration No. 43,966

WOODCOCK WASHBURN LLP
One Liberty Place - 46th Floor
Philadelphia, PA 19103
Telephone: (215) 568-3100
Facsimile: (215) 568-3439



| | | | |
|---|----|--|-------------------------------|
| Form PTO-1449 Modified List of Patent and Publications Cited by Applicant (Use several sheets if necessary) U.S. Department of Commerce Patent and Trademark Office | | Docket No. CEPH-2249/ CP241 | Application No. 10/616,776 |
| | | Applicant Craig Heacock, et al. | |
| | | Filing Date July 10, 2003 | Group 1615 |
| | | Confirmation No. 1994 | |
| OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.) | | | |
| | 21 | Becue T. et al., "Confirmation of the Structure of By-Products in the Synthesis of Modafinil by Liquid Chromatography-Mass Spectrometry," <i>J. of Chromatography</i> , 1991 , 557, 489-494 | |
| | 22 | Carlson, R.F., et al., "Efficacy and safety of reformulated, micronized glyburide tablets in patients with non-insulin-dependent diabetes mellitus: a multicenter, double-blind randomized trial," <i>Clin Ther</i> , 1993 , 15(5), 788-796 | |
| | 23 | Drabowicz J. et al., "A convenient procedure for the oxidation of sterically hindered sulfides to sulfoxides," <i>Synthesis</i> , 1990 , 937 – 938 | |
| | 24 | Drouin J.E. et al., "Optimization of the Mobile Phase for the Liquid Chromatographic Separation of Modafinil Optical Isomers on a Chiral-AGP Column," <i>J. of Chromatography</i> , 1992 , 605, 19-31 | |
| | 25 | <i>Drugs of the Future</i> ; "Modafinil," 1990 , 15(2), 130-132 | |
| | 26 | FDA/CDER guidance document "Dissolution Testing of Immediate Release Solid Oral Dosage Forms," 1997 , 1-11, A-1 – A-2 | |
| | 27 | FDA/CDER guidance document "Immediate Release Solid Dosage Forms: Scale-up and Post Approval Changes (SUPAC-IR): Chemistry, Manufacturing and Controls, In Vitro Dissolution Testing and In Vivo Bioequivalence Documentation," 1995 , 1-26, A1 | |
| | 28 | Fuxe K. et al., "Evidence for a Protective Action of the Vigilance Promoting Drug Modafinil on the MPTP-Induced Degeneration of the Nigrostriatal Dopamine Neurons in the black mouse: an immunocytochemical and biochemical analysis," <i>Exp Brain Res</i> , 1992 , 88, 117-130 | |
| | 29 | Haleblan J.K., "Characterization of Habits and Crystalline Modification of Solids and Their Pharmaceutical Application," <i>Journal of Pharmaceutical Sciences</i> , 1975 , 64(8), 1269-1288 | |
| | 30 | Hargrove, J.T., et al., Absorption of oral progesterone is influenced by vehicle and particle size," <i>Am. J. Obstet. Gynecol.</i> , 1989 , 948-951 | |
| EXAMINER | | DATE CONSIDERED | |

| | | | |
|---|----|---|-------------------------------|
| Form PTO-1449 Modified List of Patent and Publications Cited by Applicant (Use several sheets if necessary) U.S. Department of Commerce Patent and Trademark Office | | Docket No. CEPH-2249/ CP241 | Application No. 10/616,776 |
| | | Applicant Craig Heacock, et al. | |
| | | Filing Date July 10, 2003 | Group 1615 |
| | | Confirmation No. 1994 | |
| OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.) | | | |
| | 31 | Hörter D., et al., "Influence of Physicochemical Properties On Dissolution Of Drugs In The Gastrointestinal Tract," <i>Adv Drug Deliv Rev</i> , 2001 , 46(1-3), 75-87 | |
| | 32 | Keese, R. et al. <i>Fundamentals of Preparative Organic Chemistry</i> 1982, Ellis Horwood Ltd., XP002310738 pp. 18-20 | |
| | 33 | Kondo, N., et al., "Pharmacokinetics of a micronized, poorly water-soluble drug, HO-221, in experimental animals," <i>Biol Pharm Bull</i> , 1993 , 16(8), 746-800 | |
| | 34 | Lauharanta, J., et al., "Pharmacokinetics of 8-methoxypsoralen in serum and suction blister fluid," <i>Arch Dermatol Res</i> , 1982 , 273(1/2), 111-114 | |
| | 35 | Lyons T.J. et al., "Modafinil: The Unique Properties of a New Stimulant," <i>Aviation, Space & Environ Med</i> , 1991 , 432-435 | |
| | 36 | McInnes, G.T., et al., "Effect of micronization on the bioavailability and pharmacologic activity of spironolactone," <i>J Clin Pharmacol</i> , 1982 , 22(8), 410-417 | |
| | 37 | Milhaud C., et al., "Effects of Modafinil, An Alpha I Adrenergic Type Psychostimulant on the Sleep of Monkeys," <i>Psychopharmacology</i> , 1988 , 96, Abstract No. 31.05.09 | |
| | 38 | Milhaud C.L. et al., "Presentation of d'un Nouveau Stimulant:Le CRL-40476," <i>AGARD Conf. Proc.</i> , 1987 , 415, 5-1 - 5-7 | |
| | 39 | Moachon G. et al., "Simultaneous Determination of Modafinil and its Acid Metabolite by High-Performance Liquid Chromatography in Human Plasma," <i>J of Chromatography B</i> , 1994 , 654, 91-96 | |
| | 40 | Ravin, L.J., "Preformulation," <i>Remington's Pharmaceutical Sciences</i> , 16 th Ed., 1980 , Chapter 75, 1355-1368 | |
| EXAMINER | | DATE CONSIDERED | |

| | | | |
|---|----|--|-------------------------------|
| Form PTO-1449 Modified List of Patent and Publications Cited by Applicant (Use several sheets if necessary) U.S. Department of Commerce Patent and Trademark Office | | Docket No. CEPH-2249/ CP241 | Application No. 10/616,776 |
| | | Applicant Craig Heacock, et al. | |
| | | Filing Date July 10, 2003 | Group 1615 |
| | | Confirmation No. 1994 | |
| OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.) | | | |
| | 41 | Remington's Pharmaceutical Sciences, 16 th Ed., 1980, 305-306 | |
| | 42 | Ripple, E.G., "Powders," Remington's Pharmaceutical Sciences, 16 th Ed., 1980, Chapter 88, 1535-1545 | |
| | 43 | Roze C., et al., "Drug CRL 40 028-Induced Inhibition of Pancreatic Secretion in Rats," Arch Int Pharmacodyn, 1983, 265, 119-127 | |
| | 44 | Shah V.P. et al., "In Vitro Dissolution Profile Comparison – Statistics and Analysis of the Similarity Factor, f ₂ ," Pharmaceutical Research, 1998, 15(6), 889-896 | |
| | 45 | Sheperd, J., "The fibrates in clinical practice: focus on micronised fenofibrate," Atherosclerosis, 1994, 110(Suppl), S55-S63 | |
| | 46 | Stolk, L.M.L., et al., "Comparison of bioavailability and phototoxicity of two oral preparations of 5-methoxypsoralen," British J. of Dermatology, 1985, 112, 469-473 | |
| | 47 | Treffel, P., et al., "A new micronized 5-methoxypsoralen preparation," Acta Derm Venerol, 1992, 72, 65-67 | |
| | 48 | Wadke D.A., et al., "Preformulation testing," Pharmaceutical Dosage Forms: Tablets, 2 nd Ed., 1989, 1-73 | |
| | 49 | Wilson et al., Textbook of Organic Medicinal and Pharmaceutical Chemistry, 6 th Ed., J.B. Lippincott Company, 1971, 386-387 | |
| | | | |
| | | | |
| | | | |
| EXAMINER | | DATE CONSIDERED | |

| | | |
|---|------------------------------------|-------------------------------|
| Form PTO-1449 Modified List of Patent and Publications Cited by Applicant (Use several sheets if necessary) U.S. Department of Commerce Patent and Trademark Office | Docket No. CEPH-2249/ CP241 | Application No. 10/616,776 |
| | Applicant Craig Heacock, et al. | |
| | Filing Date July 10, 2003 | Group 1615 |
| | Confirmation No. 1994 | |

U. S. PATENT DOCUMENTS

| Examiner Initial | | Document No. | Date | Name | Class | Subclass |
|------------------|----|--------------|----------|------------------------|-------|----------|
| | 50 | 4,002,718 | 01/11/77 | Gardella et al. | 424 | 37 |
| | 51 | 4,122,157 | 10/24/78 | Huber | 424 | 21 |
| | 52 | 4,196,188 | 04/01/80 | Besins | 424 | 37 |
| | 53 | 4,332,721 | 06/01/82 | Bernini | 260 | 239.57 |
| | 54 | 4,517,179 | 05/14/85 | Raghunathan | 514 | 249 |
| | 55 | 4,713,246 | 12/15/87 | Begum et al. | 424 | 455 |
| | 56 | 4,880,623 | 11/14/89 | Piergiorgio et al. | 424 | 465 |
| | 57 | 4,895,726 | 01/23/90 | Curtet et al. | 424 | 456 |
| | 58 | 5,021,242 | 06/04/91 | Romer et al. | 424 | 436 |
| | 59 | 5,202,129 | 04/13/93 | Samejima et al. | 424 | 489 |
| | 60 | 5,618,845 | 04/08/97 | Grebow et al. | 514 | 618 |
| | 61 | 2004/0167255 | 08/26/04 | Lee et al. | 524 | 100 |
| | 62 | 2004/0105891 | 06/03/04 | Bentolila et al. | 424 | 489 |
| | | | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |
| EXAMINER | | | | DATE CONSIDERED | | |

| | | |
|---|------------------------------------|-------------------------------|
| Form PTO-1449 Modified List of Patent and Publications Cited by Applicant (Use several sheets if necessary) U.S. Department of Commerce Patent and Trademark Office | Docket No. CEPH-2249/ CP241 | Application No. 10/616,776 |
| | Applicant Craig Heacock, et al. | |
| | Filing Date July 10, 2003 | Group 1615 |
| | Confirmation No. 1994 | |

FOREIGN PATENT DOCUMENTS

| Examiner Initial | | Document No. | Date | Country | Translation | |
|---------------------|----|-------------------|----------|------------------------|-------------|--------------------------|
| | | | | | YES | NO |
| | 63 | WO 94/21371 A1 | 09/29/94 | PCT | X abstract | |
| | 64 | WO 95/00132 A1 | 01/05/95 | PCT | X abstract | |
| | 65 | WO 95/01171 A1 | 01/12/95 | PCT | X abstract | |
| | 66 | WO 02/10125 A1 | 02/07/02 | PCT | | |
| | 67 | WO 2004/004692 A1 | 01/15/04 | PCT | | |
| | 68 | 0 097 071 B1 | 08/28/85 | EP | | X abstract not available |
| | 69 | 0 233 106 B1 | 05/31/89 | EP | X abstract | |
| | 70 | 0 462 004 B1 | 09/06/95 | EP | X abstract | |
| | 71 | B 2 385 693 | 10/27/78 | FR | X abstract | |
| | | | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |
| EXAMINER | | | | DATE CONSIDERED | | |